DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

HFA 305

AUG 22 2005

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Deborah A. Jaskot
Vice President, Regulatory Affairs
Teva Pharmaceuticals USA
1090 Horsham Road
North Wales, PA 19454

Re: Docket No. 2005P-0079/CP1

Dear Ms. Jaskot:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on February 22, 2004. Your petition requests that the Agency determine whether Vioxx tablets (12, 25, and 50 mg.) sponsored by Merck & Co., Inc. were voluntarily withdrawn or withheld from sale for reasons other than safety or efficacy.

FDA has yet to reach a decision on your petition because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2005P-0079

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